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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,571	08/20/2003	Robert Hugh McKenna	END-5106 -515143	6638
26874	7590	09/09/2005	EXAMINER	
FROST BROWN TODD, LLC 2200 PNC CENTER 201 E. FIFTH STREET CINCINNATI, OH 45202			ISABELLA, DAVID J	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/644,571

Applicant(s)

MCKENNA ET AL.

Examiner

DAVID J. ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 20-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Applicant's election with traverse of claims 1-19 in the reply filed on 6/13/2005 is acknowledged. The traversal is on the ground(s) that there are not two or more independent and distinct inventions. This is not found persuasive because the apparatus as claimed does not require utilization in the manner as set forth in the method steps of claims 20-25; and conversely, the method steps do not require the specifics of the apparatus as set forth in claims 1-19. Therefore, the search for the method does not require the search for the apparatus and the search for the apparatus does not require the search for the method.

The requirement is still deemed proper and is therefore made FINAL.

Claims 20-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/13/2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Specification

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The disclosure is objected to because of the following informalities: claim 1 requires the function of the tube wall to "operative"ly separate digestive secretions from the food in the small intestine. As worded it appears that the wall inherently possess some mechanism for operatively removing the secretion from the food particles, however, it is unclear from the specification that the wall performs no other function than redirecting secretions from the small intestine. It appears by "operative" applicant is merely establishing a fluid connection between two points and the wall, being impermeable, prohibits the secretion from entering the small intestine. If this is the case, the wall is merely a passive agent and the tube when placed in vivo serves to provide the function of bypassing the secretion and not "the wall" per se.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8,10-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Levine (2004/0249312 or 2004/0220682). Each of Levine disclose:

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an apparatus for diverting digestive secretions, the apparatus comprising a tube

- a) a proximal end which when deployed is operative to receive digestive secretions,
- b) a distal end which when deployed is operative to discharge the digestive secretions, and
- c) a tube wall having an inner surface and an outer surface, the tube wall inner surface defining passage extending between the proximal and distal ends, wherein when deployed the passage is operative to transfer the digestive secretions from the proximal end to the distal end.

Claims 2 and 3, "the secretion" is not part of the "apparatus" as the secretion is more appropriately directed to a method for providing a fluid channel for moving secretion. Therefor, the limitations of bile or pancreatic secretion fails to positively further limit the structure of the apparatus as claimed.

Claim 4, see stents 360,460,560 of Levine '682 and 216 of Levine '312.

Claims 5-8, "attachment to various anatomical lumen" is not part of the "apparatus" as the anatomical lumen is more appropriately directed to a method for providing a fluid channel for moving secretion. Therefor, the limitations of the ampulla, bile duct, pancreatic duct and duodenum fails to positively further limit the structure of the apparatus as claimed.

Claim 10, see sleeve configuration of the stents of Levine.

Claims 11 and 12, see permeability characteristics as disclosed by Levine, see paragraphs [0037] and [0064].

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Claim 13, since there is limited permeability in the devices of Levine, the tube inherently exhibits an osmotic gradient.

Claim 14, see rejection to claim 1 supra.

Claims 15-19, see rejections to claims 5-8 supra. The device of Levine has a predetermined length.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipate by Ryan et al (6576009).

Ryan et discloses :

an apparatus comprising a tube a) a proximal end which when deployed in a lumen,

b) a distal end, and

c) a tube wall having an inner surface and an outer surface, the tube wall inner surface defining passage extending between the proximal and distal ends, wherein when deployed the passage is operative to transfer fluid from the proximal end to the distal end.

Claims 2 and 3, "the secretion" is not part of the "apparatus" as the secretion is more appropriately directed to a method for providing a fluid channel for moving secretion. Therefor, the limitations of bile or pancreatic secretion fails to positively further limit the structure of the apparatus as claimed. As broadly claimed, the apparatus is a tube that allows fluid to flow from one end thereof out of the second end thereof.

Claim 4, see stents of Ryan et al.

Claims 5-8, "attachment to various anatomical lumen" is not part of the "apparatus" as the anatomical lumen is more appropriately directed to a method for providing a fluid channel for moving secretion. Therefor, the limitations of the ampulla, bile duct, pancreatic duct and duodenum fails to positively further limit the structure of the apparatus as claimed.

Claim 9, see Y-shaped stent of Ryan et al.

Claim 10, see sleeve configuration of the stents of Ryan et al.

Claims 11 and 12, see permeability characteristics as disclosed by Ryan et al.

Claim 13, since there is limited permeability in the devices of Ryan et al, the tube inherently exhibits an osmotic gradient.

Claim 14, see rejection to claim 1 supra.

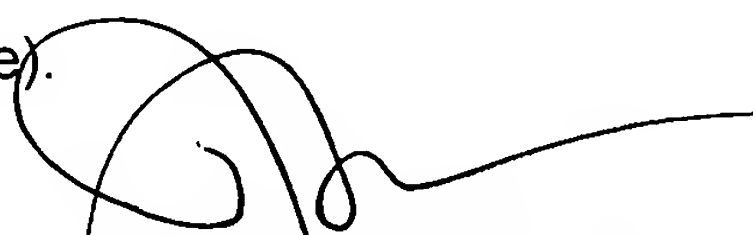
Claims 15-19, see rejections to claims 5-8 supra. The device of Ryan et al has a predetermined length.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-THURSDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

DJI
9-4-2005